



**Brussels, 22 September 2025  
(OR. en)**

**13066/25**

**COMPET 900  
IND 366  
INTER-REP 92**

**NOTE**

---

From:	General Secretariat of the Council
To:	Delegations
Subject:	Presentation by European Biosolutions Coalition (agenda item 3.) at the Working Party on Competitiveness and Growth (Industry) on 22 September 2025

---

Delegations will find attached a presentation by European Biosolutions Coalition, delivered at the meeting of the Working Party on Competitiveness and Growth (Industry) on 22 September 2025.

This document contains a presentation by an external stakeholder and the views expressed therein are solely those of the third party it originates from. This document cannot be regarded as stating an official position of the Council. It does not reflect the views of the Council or of its members.

# European Biosolutions Coalition

COMPET Working Party 22 September  
2025

Andreas Gram Drachmann, Senior Advisor, European  
Biosolutions Coalition (ANGD@di.dk)



# What is the European Biosolutions Coalition?

- A Coalition of like-minded and ambitious national industry organizations
- **Purpose:** To highlight the importance of streamlining the regulatory framework for biosolutions in the EU and member states
- **Goal:** To have strong ambitions on biosolutions included in the upcoming European Biotech Act



2

# Company presentations on behalf of European Biosolutions Coalition

## Novonesis:

Presenter: Johan Weimann

## Contact persons:

Peter Steen Mortensen - [pstm@novonesis.com](mailto:pstm@novonesis.com)

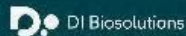
Teis Brüel Birkegaard - [TEBI@novonesis.com](mailto:TEBI@novonesis.com)

## Austrocel:

Dr. Christian Hutterer - [christian.hutterer@austrocel.com](mailto:christian.hutterer@austrocel.com)

## Biotalys:

Eva Van Hende - [eva.vanhende@biotalys.com](mailto:eva.vanhende@biotalys.com)



# Competitiveness of Biosolutions

Case: Enzymes

Copyright © 2025 Novonesis Group. All rights reserved.

## Novonesis by the numbers



**+10,000**  
employees worldwide



**+30**  
industries served



**~2,000**  
people in R&D



**~40**  
R&D and application centers



**+30**  
production sites



**~10,000**  
patents



**~11%**  
of revenue re-invested in R&D



**+45**  
countries we are present in

5

Copyright © 2025 Novonesis Group. All rights reserved.

**novonesis**

## Adding to resilience of EU



### **Agriculture / food**

- Increase yields
- Enhance plant resilience
- Reduce dependency on traditional fertilizer
- Reduce food waste
- Diversify sources to proteins



### **Energy**

- Reduce energy consumption in industrial processes
- Access to biofuels



### **Raw materials**

- Reduce raw materials used in industrial processes
- Enable the use of bio-based material
- Enhance circularity in production

.... and much more.

6

Copyright © 2025 Novonesis Group. All rights reserved.

**novonesis**



## Case: Enzymes

Enzymes are proteins functioning as biological catalysts.

Used across 30 industries to enhance efficiency, performance and sustainability.

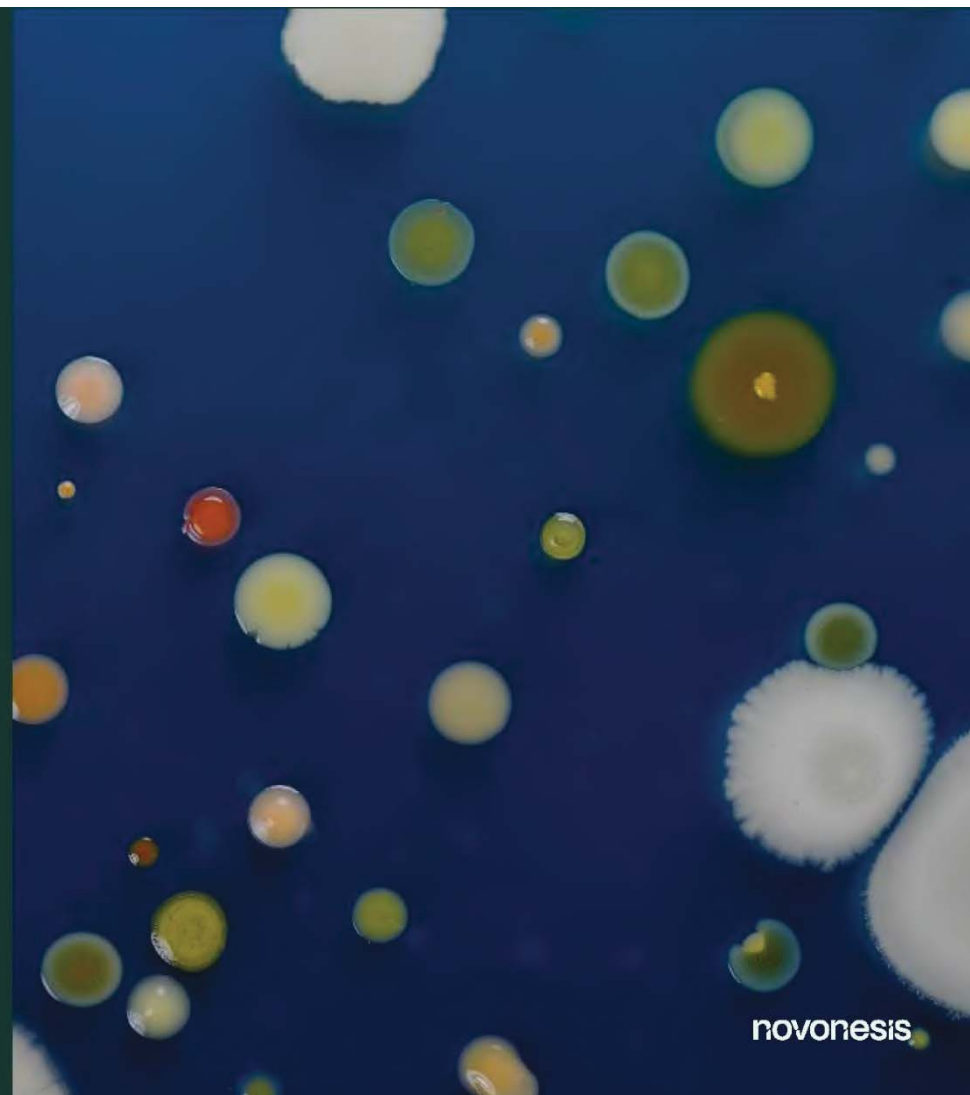
Safely used for more than 50 years.

### Problem: Unfit regulation

- Regulated as a chemical – but is biology
- No benefit assessment – only risk
- Fragmented framework – across regulation and Member States

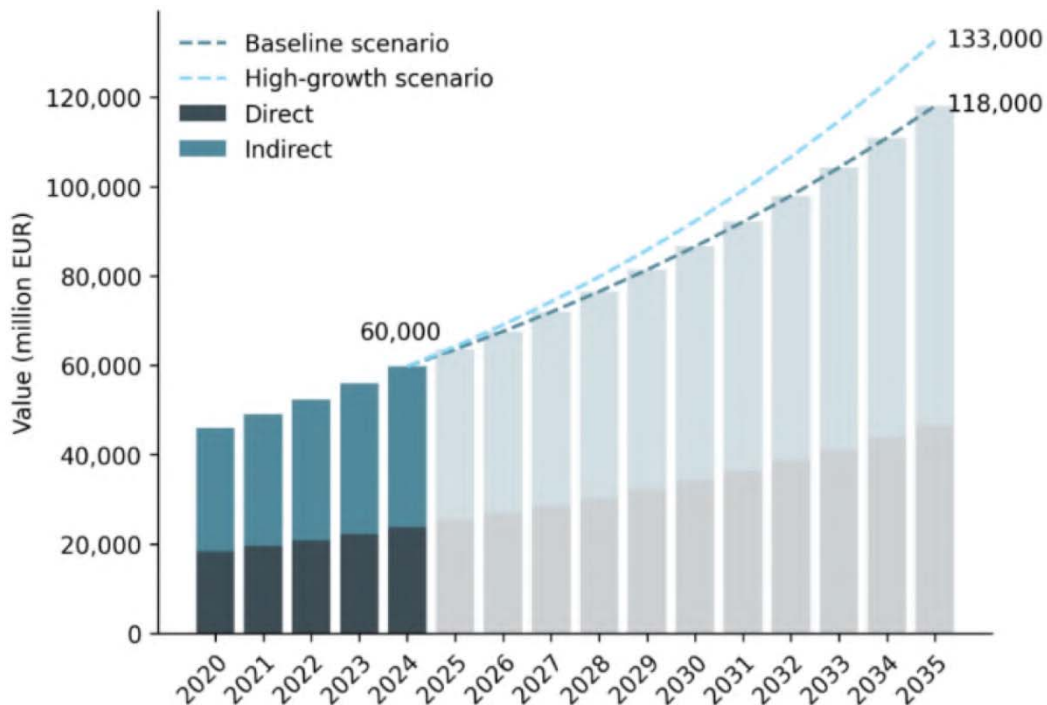
7

Copyright © 2025 Novonesis Group. All rights reserved.





# Economic Footprint of Biosolutions (EU)



ADC Report (2025); The Value of Biosolutions: Growth and Prosperity to 2035 (European Edition)

8

Copyright © 2025 Novonesis Group. All rights reserved.

## Additional economic benefits

- +600.000 jobs across EU
- 2,9 indirect job creation

## If the right policies are implemented

**Bonus:** Applying known biosolutions could reduce global emission by 8%

novonesis

## Recommendations

EU and EUMS should leverage the EU's competitive advantage in biosolutions by:

- **adopting fit-for-purpose regulation**, that reflects the characteristic of biosolutions and exempt enzymes (biosolutions) from requirements design for traditional chemicals.
- **introducing innovation-friendly regulation**, including measures to increase the risk-appetite of European investors
- **streamlining approval processes** for biosolutions in areas such as energy, agriculture and food products;
- **incentivizing uptake of biosolutions**, e.g. via public procurement as well as by rewarding energy efficiency and limiting food waste.

**BioTech Act** is a major opportunity to do this and make EU the lead market for one of the strategic technologies of tomorrow.

9

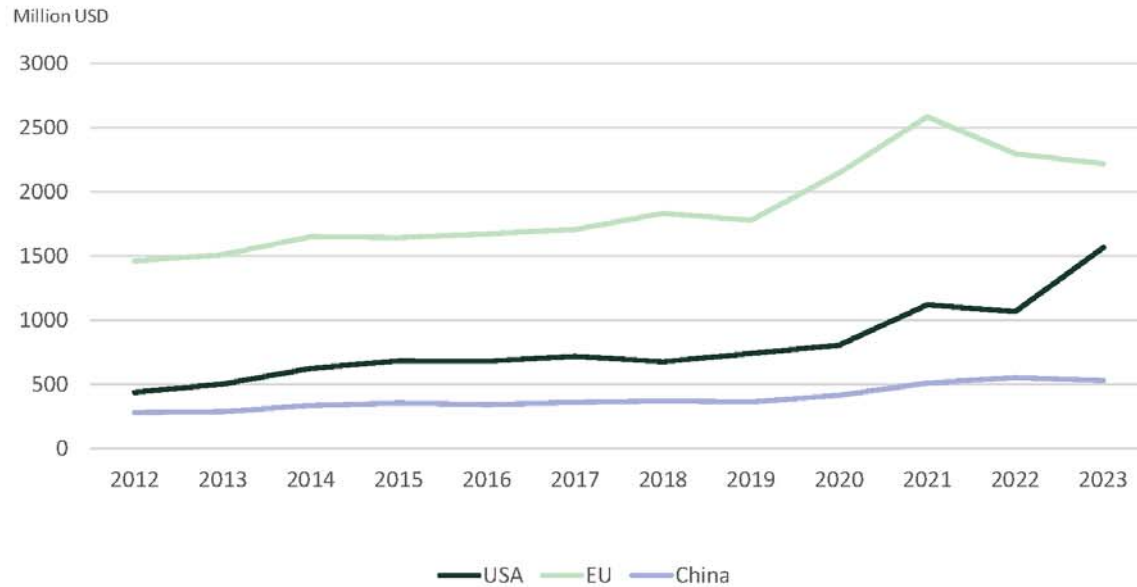
Copyright © 2025 Novonesis Group. All rights reserved.



novonesis

## Case: Enzymes

## Competitiveness: EU is losing grounds to the US



Exports to world market; Enzymes; prepared enzymes not elsewhere specified or included from (CN3507). Source: <https://trendeconomy.com/>

10

Copyright © 2025 Novonesis Group. All rights reserved.

## Trends

- EU holds the largest production capacity and is the largest exporter.
- But export data show the EU is losing ground.
- FDI trends
  - US attracts more FDI in biotech than any other economy (more than China, UK and DE combined)
  - Since 2019, approx. 55% of EU-investors biotech investments went to US

novonesis

# Questions?

novonesis

Copyright © 2025 Novonesis Group. All rights reserved.



## AustroCel Hallein GmbH – A Pioneer in Circular Economy

Eigentum von AustroCel – Vertrauliche Informationen

We unlock the power of nature.

## **Circular Business Models Are Game Changers for Traditional Industries**

**‘The Oil of the Future Is Biogenic’**



**Certainty From EU Legislation Needed for Fast green Transformation → Full Transition to Green Fuels, Make Competitiveness With Non-Renewable Fuels From Abroad Possible!**

Eigentum von AustroCel – Vertrauliche Informationen

We unlock the power of nature. 13



# Raw Materials from Sustainable Forestry

Living Biomass at the End of Its Life Cycle



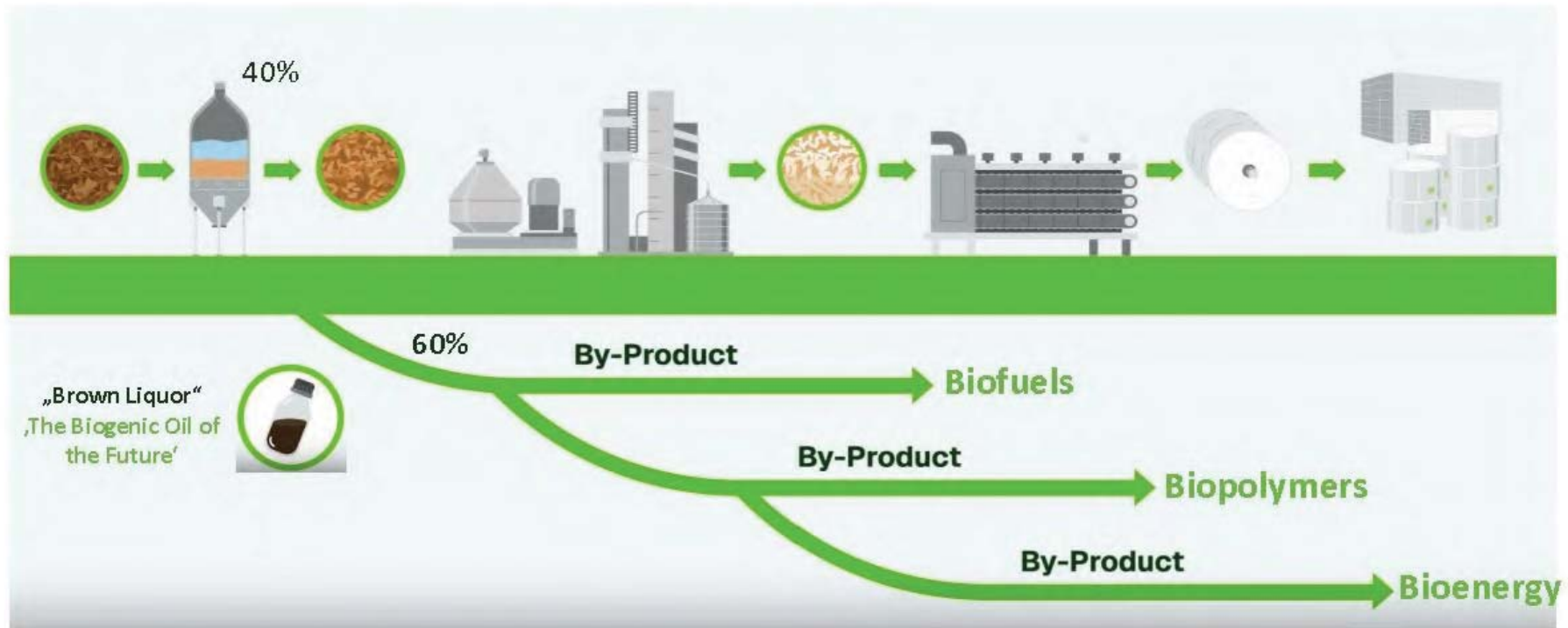
Eigentum von AustroCel – Vertrauliche Informationen

We unlock the power of nature.



# AustroCel's Transition: From a Linear Paper Production to a Modern Integrated Biorefinery

Works Circular – Full Valorization of All By-Products and Waste Streams



Eigentum von AustroCel – Vertrauliche Informationen

We unlock the power of nature.

# Political Framework Proposals

- Transformation Needs High Investments, hence Political Certainty Necessary for Transformation Projects
- The Integration of Bioprocesses into Established Process-, Chemical- or Energy Industries Could be a Specific Focus of Funding with Enormous Potential Effects and a Wide Variety of Applied Innovations. (as can be Seen in the Case of AustroCel). This Would Specifically Support Traditional Domestic Industries.
- EU Legislation Enabling Full Transition to Green Fuels (Transport Sector, SAV, Marine Biofuels), Rework Current ETS System to Make Competition with Non-Sustainable Product Alternatives on Global Markets Possible → Streamline Ticket System
- Avoid Sector Targets Which Cannot be Accomplished by European Industries and Therefore Create Dependencies on Low Cost, Questionable Imports (e.g. Lipid Feedstocks from Asia), Competing with European Value Chains. Or Introduce Sub-targets to Foster Domestic Value Generation.
- Simplify Certification Procedure for Green Chemicals Nationally and Internationally (e.g. SURE, ISCC and National Schemes on Top)
- No Delay of National Implementation of RED 3 (EU 2023/2413)!

## Topics to be Forwarded:

- EU Waste Management Law (2008/98/EG) → Biogenic Side Streams to be Classified as Feed Stock Rather than “Waste” (e.g Food Residues and Industry Sidestreams)
- EUDR: Simplify Regulation for Local Stakeholders Obtaining Wood from a Small Radius Inside Europe (Competition with Globally-Acting Timber Industry)

Eigentum von AustroCel – Vertrauliche Informationen

We unlock the power of nature.



# Biotalys' Case Study

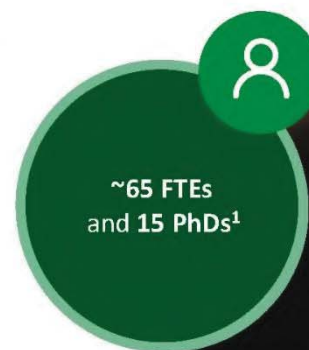
September 22<sup>nd</sup>, 2025

Eva Van Hende, Head of Regulatory, Field Development and Sustainability

17



## Key facts



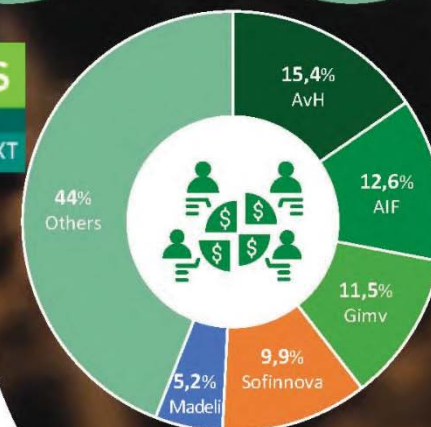
**AgTech company** developing novel  
**protein-based solutions** to protect  
crops against pests and diseases

**Antibody-based technology** already  
successfully applied in pharma

**Biotalys developed a first product,**  
**EVOCA™<sup>2</sup>**, aiming to offer fruit &  
vegetable growers a **new tool to fight**  
**major fungal diseases**

Dutch authority provided  
**recommendation for EU approval**

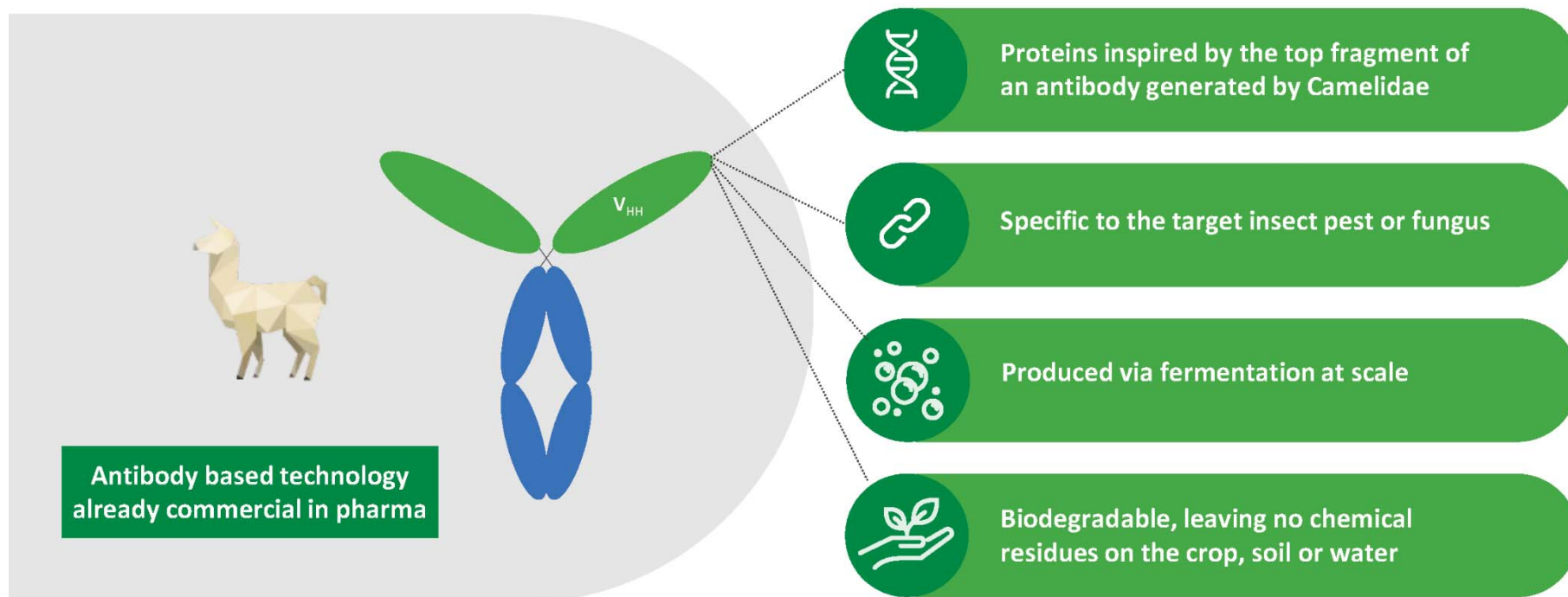
**BTLS**  
LISTED  
EURONEXT



Notes: 1. As of January 2025; 2. Regulatory review of EVOCA™ is pending. This product is not currently registered for sale or use in the European Union, the United States, or elsewhere and is not being offered for sale and no assurance can be given if and when registration will be obtained.

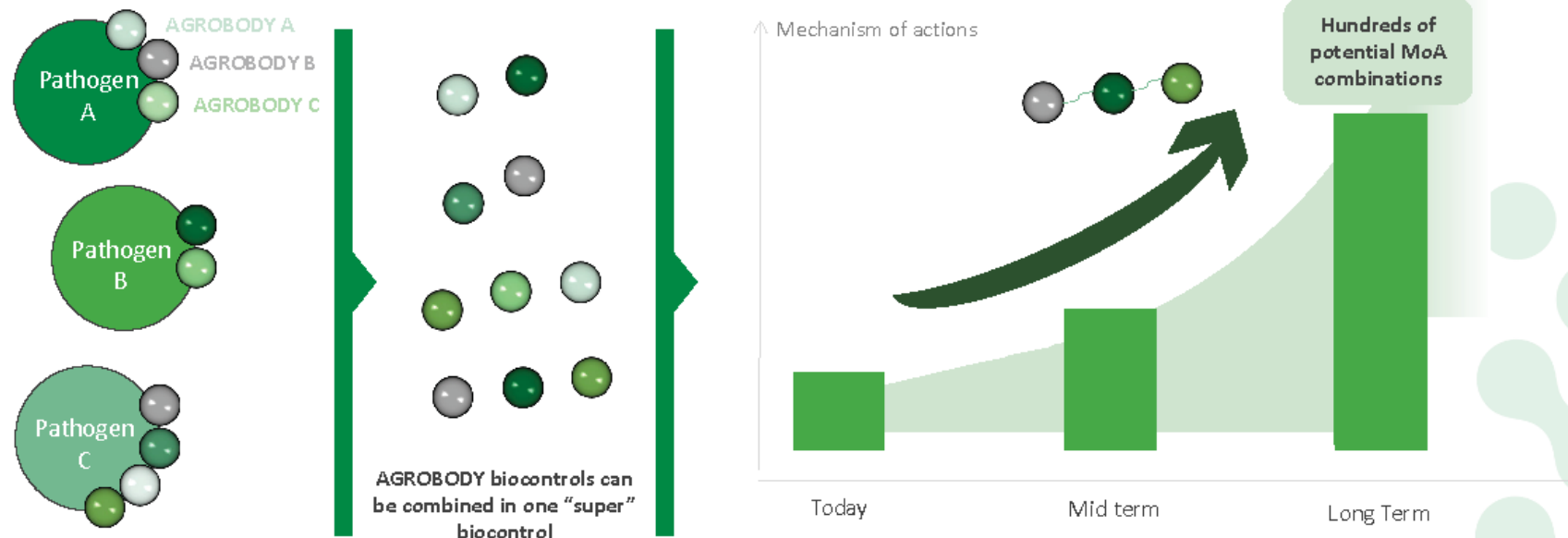
18

## AGROBODY™ technology to develop protein-based biocontrols



19

## Platform with the potential to unleash an array of combinations of different MoAs



**Biotallys is developing +10 different modes of action in the next decade, with the potential to combine these MoAs into different products and offer a multitude of unique AGROBODY biocontrol solutions by then**

Source: Data based on company's own estimates

CONFIDENTIAL - NOT FOR DISTRIBUTION

20

## The Biotech innovation Process is like



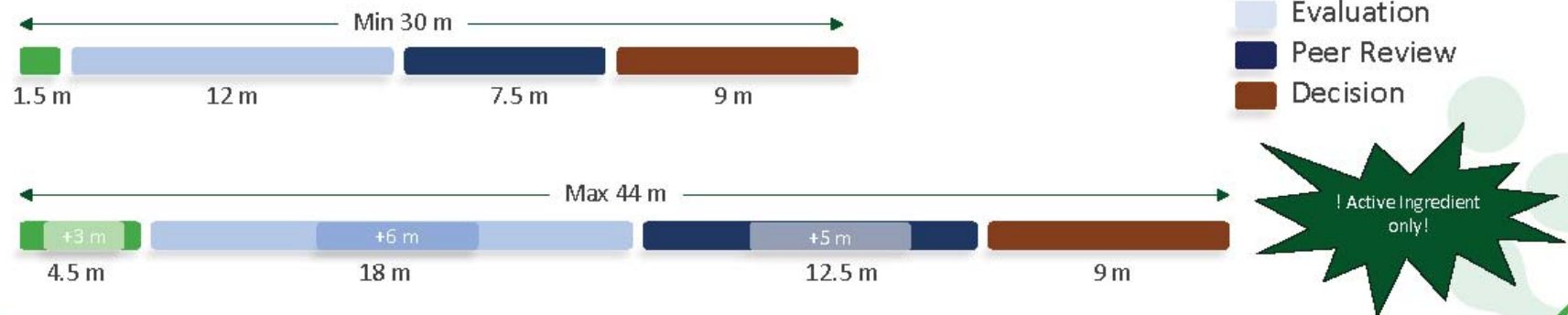
## The EU Regulatory Process is like





# Registration situation EVOCA™ Europe

## Legal timeline (Regulation 1107/2009)



## EVOCA timeline (Regulation 1107/2009)



22

# Registration situation EVOCA™ Europe



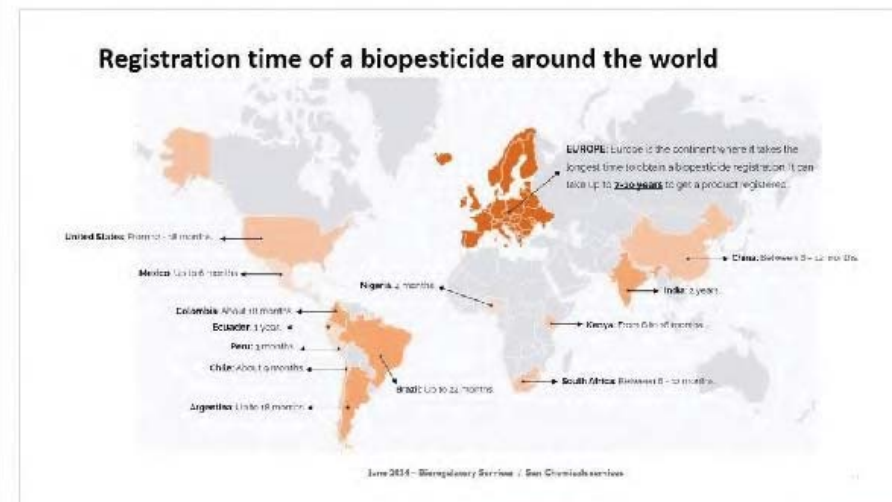
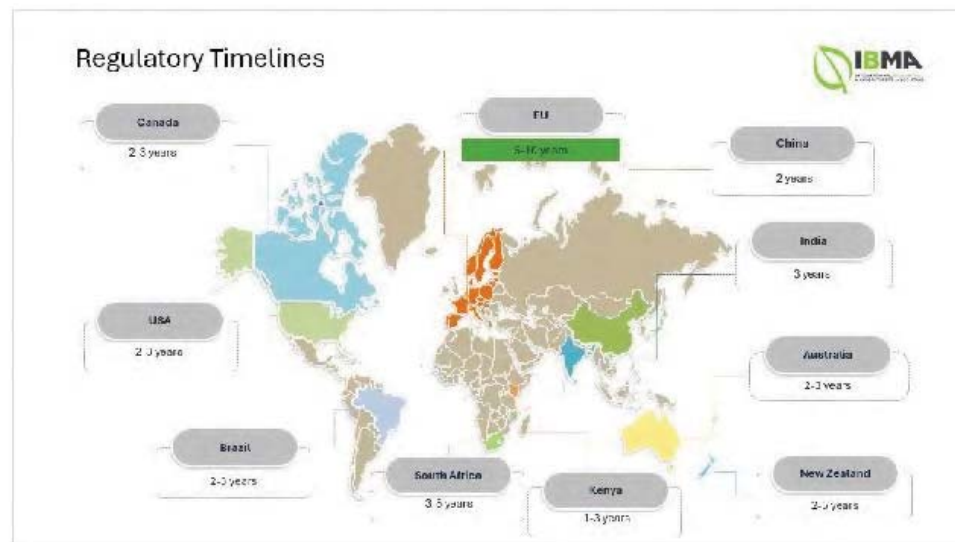
- March '21: Submission
- Sept '25: awaiting final DAR
- Legal timeline for drafting DAR: April-October '22



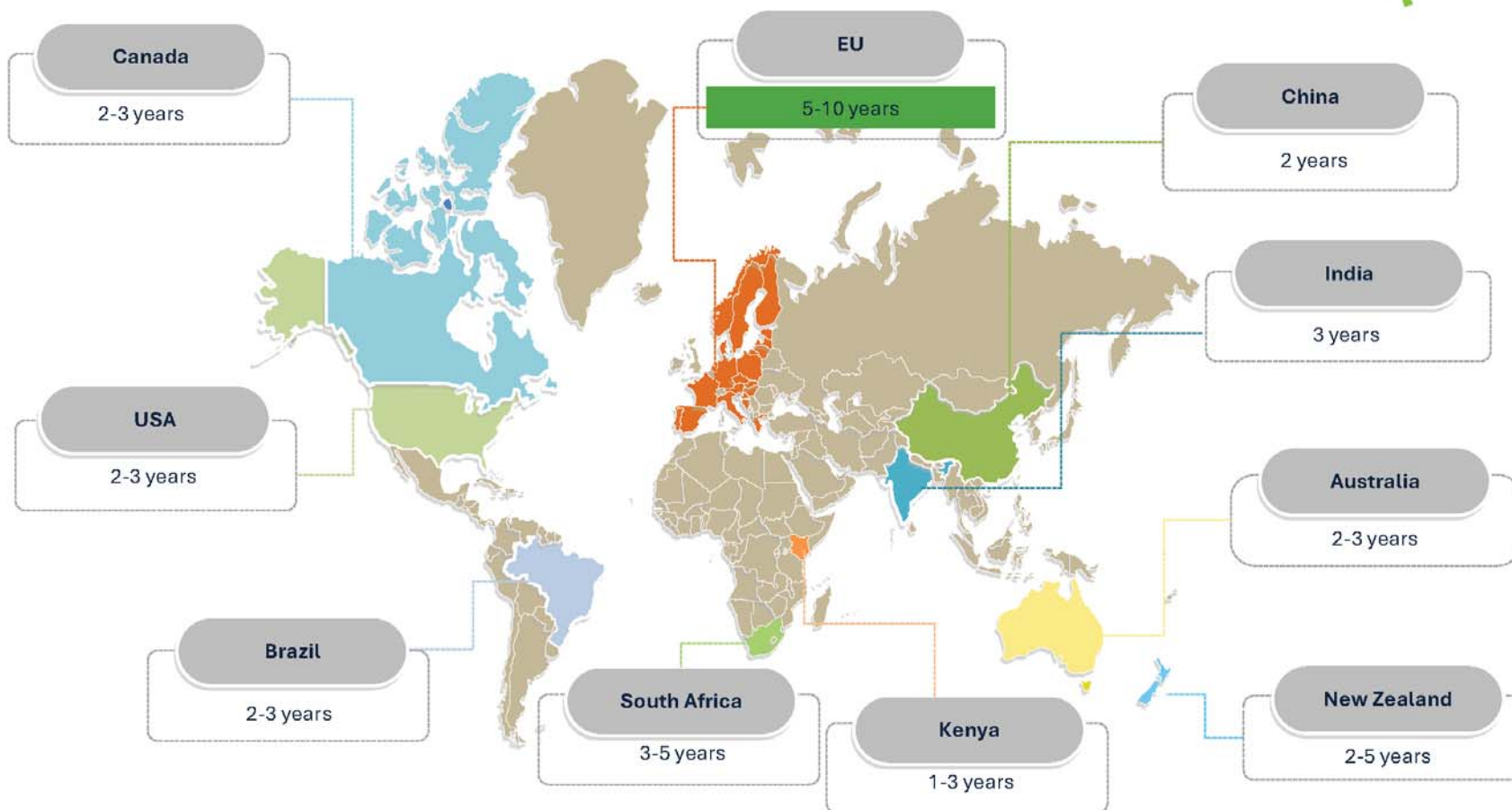
- 70 dossiers in the waiting line
- 100 decisions needed per year in next years
- Average per year: 26 decisions per year

# Current Global Regulatory Situation

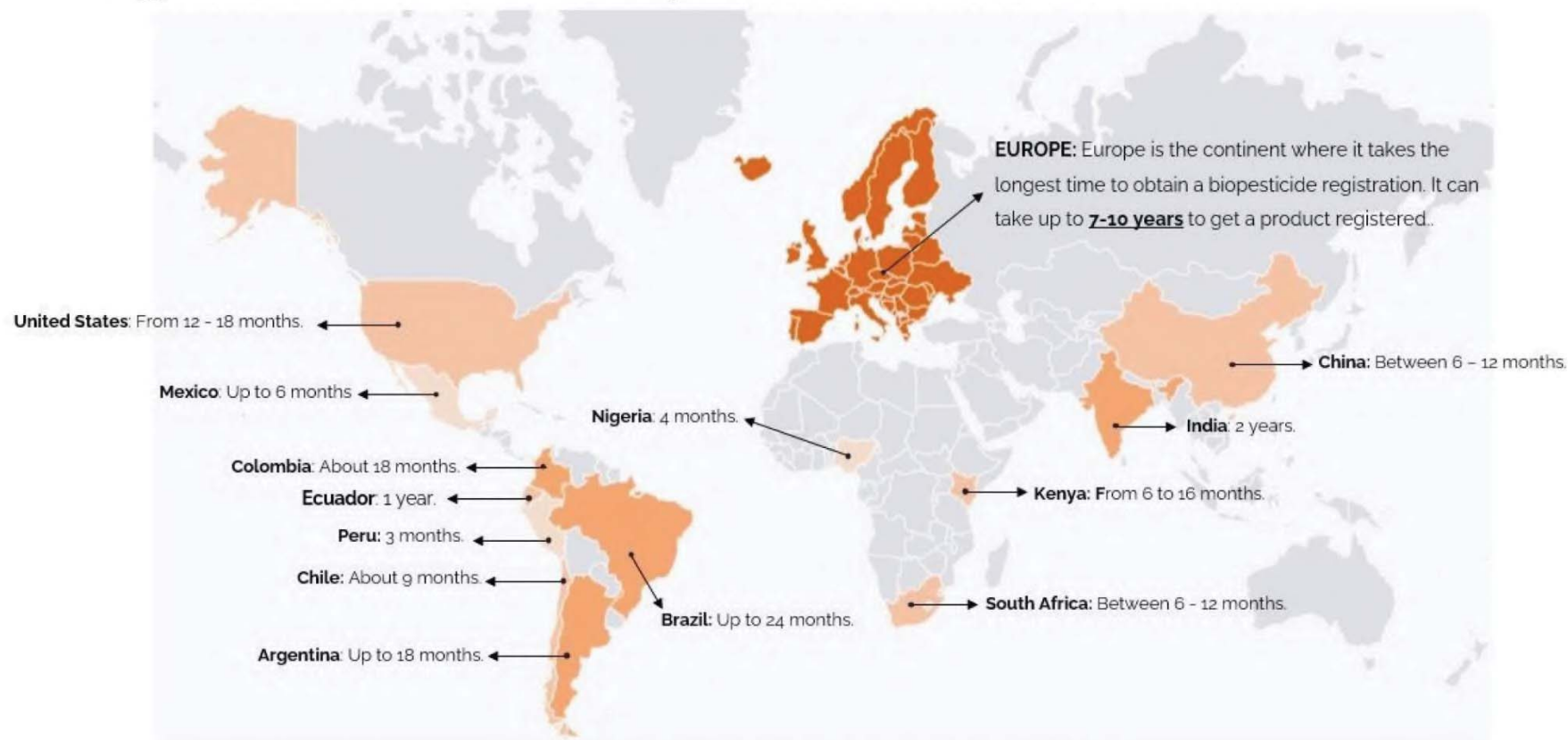
- The European regulatory process of (bio)pesticides is the slowest in the world
- The regulatory process is unpredictable, complex, expensive and long



# Regulatory Timelines



# Registration time of a biopesticide around the world



June 2024 – Bioregulatory Services / Sun Chemicals services

77



# Thank you

